

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Docket Nos. 030-06068; 030-33798

License Nos. 37-02401-01; 37-02401-06G

Registration Nos. NR-504-D-109-G; NR-504-D-109-G

Report Nos. 030-06068/97-001; 030-33798/97-001

Licensee: Nuclear Research Corporation

Location: 125 Titus Avenue
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Date: December 22, 1997

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RETURN ORIGINAL TO
REGION I

EXECUTIVE SUMMARY

Nuclear Research Corporation
NRC Inspection Report 030-06068/97-001 and 030-33798/97-001

This special announced inspection included a review of the manufacturing, distribution, and servicing of generally licensed devices, and review of the quality assurance program. The scope of the inspection included review of the authorized licensed activities stated above with emphasis on distribution of devices in accordance with their registration certificates.

Manufacturing, Distribution, and Servicing

The licensee appears to be distributing gauges which are in compliance with their registration certificates and licenses, with the exception of one issue. The licensee has distributed gauge models for use under specific licenses that are currently registered only for use under a general license. In order for the licensee to distribute the currently registered devices for use under a specific license, the licensee must submit a request to the NRC to have the registration certificate amended.

Quality Assurance and Control Programs (QA Program)

Although a QA program was referenced as an attachment to one of the letters submitted to the NRC as part of its license and device registration applications, neither the NRC nor the licensee was able to locate a copy of the document. It was therefore not possible to determine whether the licensee was implementing the QA program as provided to, and as previously approved by, the NRC. Alternatively, the inspection team performed a brief review of the licensee's current QA program. This review indicated that the current QA program adequately addresses critical QA issues. The licensee was directed that they must submit a copy of the current QA program to the NRC for review and approval, and in the future, that they must receive NRC approval for any changes to the QA program before implementing those changes.

REPORT DETAILS

I. Scope

Nuclear Research Corporation currently possesses two NRC licenses. License No. 37-02401-01 authorizes possession of any byproduct material with atomic numbers 1 through 83 as well as americium-241 sealed sources incident to the distribution of nuclear gauging devices. This license also authorizes manufacturing, and servicing of these devices. Nuclear Research Corporation also possesses License No. 37-02401-06G which authorizes the distribution of registered gauges for use under a general license.

Nuclear Research Corporation has three active registration certificates: NR-504-D-109-G (Model SH-300 series), NR-504-D-111-G (Model LS-101), and NR-504-D-117-S (Model NRC-D-701049). Registration certificate NR-504-D-117-S is for a chemical agent detector that is custom registered to the U.S. Army. Quality Assurance/ Quality Control (QA/QC) for this product is controlled by Army contract, which specifies acceptable specifications (mil specs and standards), and is monitored by a resident government Quality Assurance Representative. Given these facts, the scope of this inspection did not include review of activities related to this registration certificate. The remaining two active certificates are for gauging devices to be used under a general license. These gauges are permanently mounted in industrial environments and are used for continuous level or density measurements. Nuclear Research Corporation currently has no active registration certificates for commercial distribution devices intended for use under a specific license. Nuclear Research Corporation also has thirteen inactive registration certificates.

The scope of the inspection included review of the authorized licensed activities stated above with emphasis on distribution of devices in accordance with their registration certificates.

II. Manufacturing, Distribution, and Servicing**a. Inspection Scope**

The inspection team discussed Nuclear Research Corporation's procedures for distribution, servicing, installation, and repair of gauges. The inspectors reviewed customer lists. No field service reports were available for review since the licensee reported that it has had no reports of problems, incidents, failures, or maintenance service for their devices, with the exception of routine wipe tests.

The inspection team reviewed the manufacturing program, reviewed selected engineering drawings used by the licensee to manufacture the devices, and inspected samples of selected parts in inventory.

b. Observations and Findings

The licensee is manufacturing and distributing gauging systems that include a source housing that was previously manufactured by Accuray Corporation. The licensee has hundreds of devices in storage so that they have not had to make any new source housings to date. The manufacturing process to date is limited to refurbishing an

existing device and adding the electronic component on the detector end. All components used in the refurbishing are from back stock purchased from Accuray Corporation when Nuclear Research Corporation took over the product line. No distribution of devices occurred between 1991 and 1996. In the past year, approximately 33 SH-300 series devices were distributed and 2 LS-101 devices were distributed. Most of the devices were sold to general licensees, but there were two cases where gauges were sold to specific licensees. In June and September 1997, fifteen SH-301 devices and six SH-352 devices, respectively, were shipped to a user for use under a specific license.

The engineering drawings for these devices that were distributed were compared to the respective registration certificates. The spare parts measured by the inspectors were within tolerance when compared to the engineering drawings provided for the registration certificate. Examples of parts that were measured include the bolts, knob actuator, linkage arm, mounting bracket, and roll pins. Several measurements of each part were taken with the licensee's calipers and were compared to the original drawings.

The licensee stated that they have not had any service calls for their devices. They have never seen a source shutter stuck. They further stated that they have not found problems with the operation of the gauges with the exception of the electronic components in the detector end of the device.

c. Conclusions

The licensee appears to be distributing gauges which are in compliance with the registration certificates, with the exception of one issue. The licensee has distributed gauge models for use under specific licenses that are currently registered only for use under a general license. In order for the licensee to distribute the currently registered devices for use under a specific license, the licensee must submit a request to the NRC to have the registration certificate amended. The current wording of the possession license, License No. 37-02401-01 does not need to be amended to reflect distribution to specific licensees.

III. Quality Assurance and Control Programs (QA Program)

a. Inspection Scope

Although a QA program was referenced as an attachment to one of the letters submitted to the NRC as part of its license and device registration applications, neither the NRC nor the licensee was able to locate a copy of the document. It was therefore not possible to determine whether the licensee was implementing the QA program as provided to, and as previously approved by, the NRC. Alternatively, the inspection team performed a brief review of the licensee's current QA program.

b. Observations and Findings

Nuclear Research Corporation's quality assurance program is very specific for newly manufactured devices or parts, however for the previous Accuray devices, the licensee

depends upon Accuray's Quality Assurance program. The inspectors noted that all of the devices the licensee distributes were previously distributed under Accuray's license and had been used out in the field. The licensee maintains a current QA manual dated October 1988.

The following is a summary of their quality assurance program:

- A. Nuclear Research Corporation keeps an inventory of spare parts. These parts were obtained from Accuray when Nuclear Research assumed the product line. The licensee stated that when these parts were first obtained, a QA check to assure that the parts matched the component drawings was performed prior to the licensee allowing them to be put into stock. The licensee recently began having one component, a screw, manufactured due to a depleted inventory. When new parts are received, they are checked against the purchase order for appropriate model numbers and quantity. A visual check is also performed to identify any damaged parts and measurements are made and documented on a physical inspection form. At the time of the inspection, the licensee had received only one shipment of these screws. Inspection of the incoming QA performed on the shipment indicated that the licensee is implementing the current QA program.
- B. Prior to a device being shipped to a customer the licensee performs a visual inspection and operational check as well as a wipe test of the device. The only dimensional check is with respect to the mounting frame. There are no specific measurements or determinations of materials of construction made to verify that the device that is shipped is the same that is registered. The licensee also performs radiation surveys around the source housing. These results are compared to expected values to determine if the shielding required is present in the source housing and to make sure there are no cracks in the shielding.

c. Conclusions

The inspection team performed a brief review of the licensee's current QA program. This review indicated that the current QA program adequately addresses critical QA issues. The licensee was directed that they must submit a copy of the current QA program to the NRC for review and approval, and in the future, that they must receive NRC approval for any changes to the QA program before implementing those changes.

IV. Management Meetings

The inspectors presented the inspection results to the company president at the conclusion of the inspection. The inspectors discussed the amendments needed to the registration certificates. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONS CONTACTED

Earl Pollock, President
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Gary Robertson, Manager Nuclear Gauging Products
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